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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,508	01/18/2005	Yongxin Han	MC060P	2000
210	7590	04/13/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/521,508

Applicant(s)

HAN ET AL.

Examiner

Yong Chu

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 1-6, and 12-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-15 are currently pending in the instant application. Applicants failed to respond to the Examiner's request in the office action dated on 2/17/2006 to elect a single compound, instead elected a list of compounds. However, the Examiner has examined all the elected species on merit.

Priority

This application is a 371 of PCT/CA03/01306 National Stage Application, filed on 25 August 2003. Applicants claim the benefit of U.S. Provisional Patent Application 60/406,530 filed on 28 August 2002.

Response to Restriction

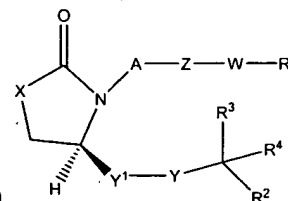
The response to the restriction request with election of Group III (e.g. claims 1-6 (in part), and 12-15 with species of compounds exemplified on lines 22 through 35 on page 10) with *traverse* by Applicants' representative, Attorney Sylvia A. Ayler dated on 15 March 2006, has been considered. Applicant's arguments on page 3-4 of the Remarks regarding the restriction requirement been fully considered but they are not persuasive. Applicant's suggested alternative groupings with election of "Group A" are considered, but are not entered because the various substituents of Z such as heteroaryl rings are structurally significant different from S, O, and CH₂ classified

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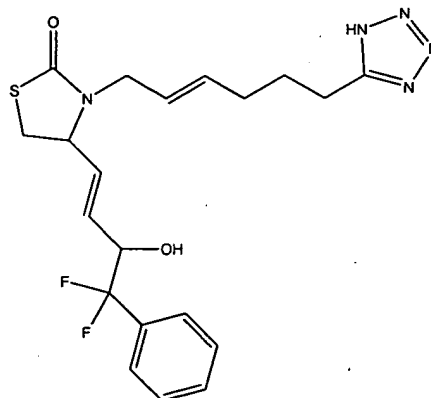
differently under U.S. Patent classification rule. They are also required different searches, especially in considering the core position of "Z" in the compound formula. It will post serious burden to the Examiner.

In accordance with M.P.EP 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. ***Failure to do so may result in a loss of the right to rejoinder.***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



The election of **Group III**, directed to products of formula (I)

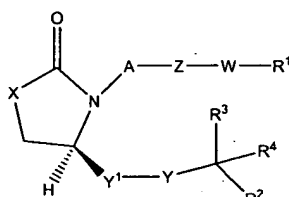


depicted in claim 1, and the specific compound, depicted in line 22-24, on page 10 of the specification, is acknowledged.

Status of the Claims

Claims 1-15 are pending in this application. Claims 7-11, and the remain subject matters of claims 1-6, and 12-15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The scope of the invention of the elected subject matter is as follows:



Compounds of formula (I) depicted in claim 1, wherein:

X is S;

Y¹ is CH₂CH₂ or CH=CH;

Y is C(O) or CH(OH);

A and **W** are independently selected from the group consisting of a bond or C₁₋₆ alkylene, unsubstituted or substituted with 1, 2, 3, or 4 halogen atoms;

Z is CH₂, CH=CH, or C ≡ C;

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R¹-R⁴ are as defined in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, claims 7-11, and the remain subject matters of claims 1-6, and 12-15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and will require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Therefore, claims 1-6 (in part) and 12-15 are examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

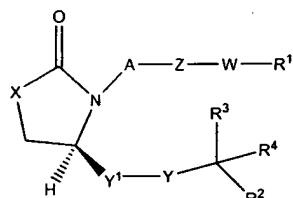
A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Kubodera *et al.*, Hetercycles (1982), vol 18, page 259-63 (See attached STN search report).

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Applicants instant elected invention in claim 1 teaches compounds of formula (I),



, depicted in claim 1, and their a pharmaceutically acceptable salts

thereof wherein:

X is S;

Y¹ is CH₂CH₂ or CH=CH;

Y is C(O) or CH(OH);

A and **W** are independently selected from the group consisting of a bond or C₁₋₆

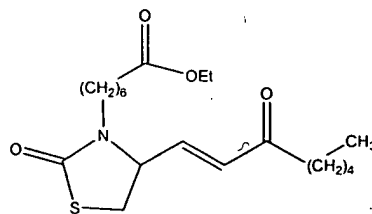
alkylene, unsubstituted or substituted with 1, 2, 3, or 4 halogen atoms;

Z is CH₂, CH=CH, or C \equiv C;

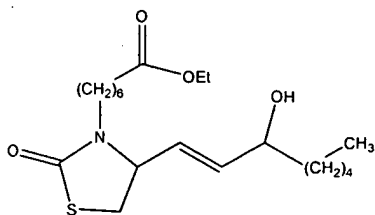
R³-R⁴ is H, halogen, or C₁-C₆ alkyl;

R¹-R² are as defined in claim 1.

Kubodera *et al.* teach specific compounds



and



, and read on the instant claim 1 wherein:

X is S;

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Y^1 is CH=CH;

Y is C(O) or CH(OH);

R^3 or R^4 is H;

R^2 is **n-butyl**, not **n-pentyl** as excluded in claim 1 of the current application;

R^1 is COR⁵, wherein R^5 is C₂-alkoxy;

A and W are unsubstituted C₁₋₆ alkylene;

Z is CH₂.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

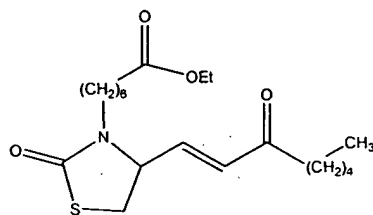
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103 (a) as unpatentable Kubodera *et al.*, Heterocycles (1982), vol 18, page 259-63 (See attached STN search report).

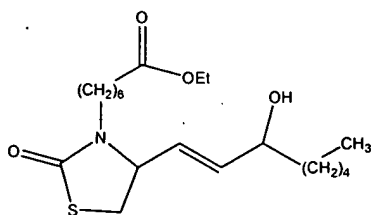
Applicants' instant elected invention in claim 1 teach a compound or a pharmaceutical formulation for treatment of disease such as Alzheimer's Disease using compounds depicted in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)

Kubodera *et al.* teach specific compounds



and



with $-(\text{CH}_2)_4\text{CH}_3$ as the end of side chain next to -

C(OH). Kubodera *et al.* do not teach all the compounds with C_{1-6} alkyl as the end of side chain as claimed in the current application.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious for combining the instantly claimed compounds with R^2 is C_{1-6} alkyl. Because One skilled in the art knows that $-(\text{CH}_2)_4\text{CH}_3$ is a species of sub-genus of C_{1-6} alkyl.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Even though claim 13 is withdrawn from consideration, the Examiner would like to bring this rejection to the Applicants' awareness for possible amendment.

Claim 13 provides for the use of a compound in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

Claim 13 is improperly dependent from Claims 1 or 6 for failure to limit the scope of claim 1 or 6. Claim 13 are drawn to compounds of claim 1 or 6 and further recite the intended use of the compounds. However, intended use is not a limitation of a compound. *In re Hack*, 114 PQ 161 (CCPA 1957). Therefore, Claim 13 is improper. By deleting claim 13, the rejection would be overcome.

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Claim 15 is improperly dependent from claim 12 for failure to limit the scope of claim 12. Claim 15 are drawn to a composition of claim 12 and further recite the intended use of the composition. However, intended use is not a limitation of a compound. *In re Hack*, 114 PQ 161 (CCPA 1957). Therefore, Claim 15 is improper. By deleting claim 15, the rejection would be overcome.

Claims 1-6, and 12-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2-6 are objected to as being contained non-elected subject matters such as the list of compounds out of elected scope. However, would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Conclusion

No claims are allowed.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759.

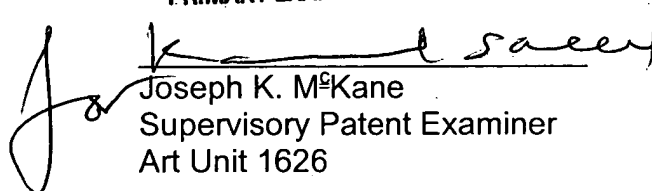
The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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